REMARKS

The Office Action of April 20, 2004 presents the examination of claims 1-9 and 11-17. Claims 1, 2, 9, 14, and 17 are amended. No new matter is inserted into the application.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 1-9 and 11-17 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

The Examiner asserts that the terms "securely maintaining" and "securely maintained" in claims 1, 2, 9, 14, and 17 are indefinite. In order to overcome the rejection, the claims are amended to recite "stably transformed with" or "stably maintained." These terms are commonly used in the art, and further are supported by the specification, such as on page 15, lines 15-19.

Applicants respectfully submit that the pending claims fully comply with 35 U.S.C. § 112, second paragraph. Withdrawal of the instant rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

The Examiner maintains the rejection of claims 1, 3-9, 11, and 13-17 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Bradfield '283 (U.S. Patent 5,650,283), in view of Waldman et al. (*Analytical Biochemistry* 258:216-222(1998)).

The Examiner maintains the rejections of claims 2 and 12 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Bradfield '283, in view of Waldman et al., and further in view of Kushner '638 (U.S. Patent 6,117,638).

Applicants respectfully traverse the rejections. Reconsideration of the claims and withdrawal of the instant rejections are respectfully requested.

The present invention provides an animal cell expressing a gene coding a ligand-responsive transcription control factor and stably transformed with a DNA comprising in a molecule, a reporter gene (a) connected downstream from a transcription control region which substantially consists of a recognition sequence of the ligand-responsive transcription control factor and a minimum promoter, and a selective marker gene (b); but does not contain a reporter gene (c). In such a cell, the constitutive background transcription activity (which hinders

the measurement of transcription activity) is lowered, such that the detection of ligand-responsive transcription activity can be conducted with higher sensitivity (see page 20, lines 11 to 13; and Example 4 of the specification).

In the Reply filed on February 9, 2004, Applicants pointed out that transformed cells of the present invention obtained by introducing DNA of pGL3-TATA-EREx5-BSD and pRC/RSV-hERα Kozak provided clones having a high ratio of luciferase activity, whereas transformed cells obtained by introducing DNA of pGL3-tk-EREx5-BSD and pRC/RSV-hERα Kozak failed to provide clones having a high ratio of luciferase activity, as shown in Example 4 of the instant specification. As such, the present invention provides an animal cell wherein ligand-responsive transcription activity can be measured with a high specificity even in the presence of constitutive background transcription activity.

In response, the Examiner states that this evidence is not persuasive because "an argument by Applicants that these constructs can confer to the claimed invention any patentable distinction over the prior art is moot, because these limitations are not in the claims." Applicants respectfully disagree.

The transformed cells of the present invention are not limited in the specific constructs shown in Example 4 of the specification. Instead, the cells of the present invention may be prepared by using a "minimum promoter," such as that described on page 17, line 7 to page 18, line 1 of the specification. The constructs disclosed in Example 4 of the specification merely represent non-limiting examples of use of a minimum promoter. These results can be obtained using a minimum promoter described in the specification.

None of the references cited (Bradfield '283, Waldman et al., and Kushner '638) teach or suggest to the ordinary skilled artisan that an animal cell stably transformed with a DNA comprising in a molecule, a reporter gene (a) connected downstream from a transcription control region which substantially consists of a recognition sequence of the ligand-responsive transcription control factor and a minimum promoter, and a selective marker gene (b), would show higher sensitivity in detection of ligand-responsive transcription activity.

Furthermore, Applicants respectfully submit that the skilled artisan would not have been motivated to combine the teachings of the references cited in order to obtain stably transformed animal cells in which ligand-responsive

transcription activity can be detected with higher sensitivity. In this regard, the motivation of Kushner relied upon by the Examiner is so general that it would never lead the skilled artisan to chose the specific promoter (i.e., minimum promoter) utilized in the present invention from the wide array of various promoters known to those of ordinary skill in the art.

For the above reasons, Applicants respectfully submit that the cited combinations of Bradfield '283 in view of Waldman et al. and Bradfield '283 in view of Waldman et al. and Kushner '638 fail to render the present invention obvious. Withdrawal of the instant rejections is respectfully requested.

Conclusion

Applicants respectfully submit that the above remarks fully address and overcome the outstanding rejections and objections. For the foregoing reasons, Applicants respectfully request the Examiner to withdraw all of the outstanding rejections, and to issue a notice of allowance indicating the patentability of the present claims. Early and favorable action of the merits of the present application is thereby respectfully requested.

If there are any minor matters precluding allowance of the application which may be resolved by a telephone discussion, the

Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of three (3) months to October 20, 2004, in which to file a reply to the Office Action. The required fee of $980.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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